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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KAZUO IWAI

Appeal 2008-2419 Application 10/006,569 Technology Center 3600

Decided: August 13, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

 ${\it GRIMES}, {\it Administrative\ Patent\ Judge}.$

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of sterilizing poultry meat. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

"Microorganism pollution of a poultry meat product occurs during transportation of poultry or at any stages in the poultry processing" (Spec. 1). "Control of microorganisms in ... processing steps is generally carried out by adjustment of temperature and pH of water for the processing, maintenance of working environments, [and] temperature control in storage and transportation" (id. at 2).

Conventional methods of sterilizing poultry meat exhibit a sterilization effect only in given steps of poultry processing for the production of poultry meat, and cannot exhibit the effect continuously in steps after a chilling step. Therefore, although a sterilization treatment is carried out, bacterial pollution and proliferation are again permitted in steps after a chilling step, so that sterilization of a product poultry meat may be insufficient in some cases.

(Id. at 3.)

The Specification discloses "a method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution in poultry processing" (id. at 3-4). Hinokitiol is "a generic name for β -thujaplicin," a compound that can be derived from white cedar leaf (id. at δ).

DISCUSSION

1. CLAIMS

Claims 11-22 and 24-27 are pending and on appeal. Claims 11, 13-15, 17, and 25-27 are representative and read as follows:

Claim 11: A method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water in poultry processing

for a production of poultry meat, wherein the contact treatment is carried out in one or more steps selected from the group consisting of an evisceration step, a chilling step and a wrapping step

wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped.

- Claim 13: The method according to claim 11, wherein the concentration of hinokitiol in the aqueous hinokitiol solution is from 1 to 50000 ppm.
- Claim 14: The method according to claim 11, wherein the aqueous hinokitiol solution has a pH of 4 to 11.
- Claim 15: The method according to claim 11, wherein the contact treatment is carried out at a temperature of 0° to 70° C.
- Claim 17: A method of sterilizing poultry meat comprising the step of subjecting poultry meat to a contact treatment with an aqueous hinokitiol solution consisting essentially of hinokitiol and water in poultry processing for a production of poultry meat, wherein the contact treatment is carried out in one or more intervals between consecutive two steps selected from the group consisting of: between an evisceration step and a chilling step and between a chilling step and a wrapping step

wherein the hinokitiol aqueous solution-contacted poultry meat is wrapped.

- Claim 25: A method for converting live poultry into sterilizing [sic], wrapped, poultry meat comprising the steps of:
 I. providing live poultry; and then
- II. killing and eviscerating the live poultry thereby producing an unsterilized carcass comprising skin, dark meat, and white meat; wherein the unsterilized carcass is contaminated with unwanted microorganisms; and then
- III. contacting the un-sterilized carcass and/or the meat with an aqueous hinokitiol solution consisting essentially of hinokitiol and water at a concentration of 1 to 50000 ppm of hinokitiol thereby:
 - (a) killing the unwanted microorganisms; and
 - (b) providing a residue of hinokitiol solution on the meat; and then

IV. wrapping the carcass and/or the meat without removal of the residue of hinokitiol solution on the meat:

thereby producing sterilizing [sic], wrapped, poultry meat without adversely affecting either the color or the taste of the meat.

Claim 26: The method according to claim 11, wherein said aqueous hinokitiol solution further contains a surfactant safe for human consumption.

Claim 27: The method according to claim 11, wherein said aqueous hinokitiol solution further contains a plant extract.

3. OBVIOUSNESS I

Claims 11-22 and 24-27 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Kurschner, ¹ Nishimoto, ² and Takahashi. ³ Claims 12 and 16 have not been argued separately from claim 11 and therefore stand or fall with claim 11, and claims 18 and 22 have not been argued separately from claim 17 and therefore stand or fall with claim 17. 37 C.F.R. § 41.37(e)(1)(vii). Claims 13-15, 19-21, and 24-27 have each been argued separately.

The Examiner relies on Kurschner as disclosing "a method of sterilizing poultry meat ... comprising the step of subjecting the poultry meat to a contact treatment with a solution," during or in the interval between processing steps, including during or between an evisceration step and a chilling step (Answer 3-4). The Examiner finds that Kurschner does not disclose "the use of the contact treatment being a hinokitiol solution" (id. at 4).

¹ Kurschner et al., US 5,632,676, May 27, 1997.

² Nishimoto et al., US 6,165,964, Dec. 26, 2000.

³ Takahashi, US 6,352,727 B1, Mar. 5, 2002.

The Examiner relies on Nishimoto as disclosing "the use of an aqueous antibacterial solution of hinokitiol for disinfection purpose (Abstract) for use in food factories" (*id.*). The Examiner relies on Takahashi as disclosing that "hinokitiol ... can also be used to treat the meat itself" (*id.*).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the antibacterial solution of Kurschner "by substituting the antibacterial solution hinokitiol as taught by Nishimoto et al. to sterilize poultry meat during processing" (id.). The Examiner reasons that "Takahashi teaches that the hinokitiol solution has a wide range of uses such as sterilizing utensils or sterilizing meat. As such this would only be the substituting of one well known sterilizing agent for another" (id.).

We conclude that the Examiner has set forth a prima facie case that claim 11 would have been obvious to the ordinary artisan. Kurschner discloses a "method for sanitizing a fowl that has been defeathered and eviscerated by contacting the fowl with [a] peracetic acid solution containing from 100 to 2000 ppm peracetic acid" (Kurschner, abstract). Kurschner also discloses that the "[p]eracetic acid solution can be applied to the fowl, such as by spraying a peracetic acid solution onto the fowl, immediately following its evisceration, or by dipping the fowl into a peracetic acid solution that is used as a chilling solution for cooling the birds" (id. at col. 3, Il. 26-31).

Nishimoto discloses a "process for the preparation of an aqueous hinokitiol solution" (Nishimoto, abstract). Nishimoto also discloses that the hinokitiol solution exhibits "broad antimicrobial spectrum to many kinds of microbials," and "can be widely used for kitchen goods such as a kitchen towel, a cutting board, and knives" (*id.* at col. 8, Il. 65 through col. 9, Il. 2). Nishimoto also discloses that the hinokitiol solution can be "used for washing hands" and shows "antibacterial spectrum for Staphylococcus, enteropathogenic *Escherichia coli*, Salmonella, and Legionella" (*id.* at col. 9, Il. 13-18).

Takahashi discloses a bactericidal composition that can contain, among other bactericides, hinokitiol (Takahashi, abstract; col. 6, ll. 26-29; col. 7, ll. 4-8). Takahashi also discloses that the bactericidal composition can be used for sterilizing meat and that "it can keep meat fresh for a long time, since it can inhibit propagation of the bacterium on the surface of the meat for a long time" (id. at col. 7, ll. 49-54).

We agree with the Examiner that it would have been prima facie obvious to one of skill in the art to combine the teachings of Kurschner, Nishimoto, and Takahashi and thereby arrive at the invention of claim 11. As discussed above, Kurschner discloses the treatment of poultry during processing (e.g., in a chilling step or after evisceration and before a chilling step) with an anti-bacterial agent. Nishimoto discloses that aqueous hinokitiol solutions are known anti-bacterial agents that may be used for kitchen goods and Takahashi discloses that a composition containing hinokitiol as an anti-bacterial agent may be used for the treatment of meat. The combination of the references would have suggested to one of skill in the art that the anti-bacterial agent, hinokitiol, could be substituted for the peracetic acid in the poultry treatment process of Kurschner because

hinokitiol is suggested as an effective anti-bacterial agent that is safe and desirable for treating meat.

Appellant argues that "one of ordinary skill in the art would not be motivated to combine the respective teachings of the cited references to arrive at the claimed invention" (Appeal Br. 13). In particular Appellant argues that "Nishimoto generally teaches the use of hinokitiol as a bacterial agent while being silent regarding poultry processing" (id.), that "Takahashi generally teaches that hinokitiol (as a minor component) may be used in conjunction with another sterilizing agent in a variety of end uses, none of which involve the sterilization of poultry meat during processing" (id. at 13-14), and that one of ordinary skill in the art "would not be directed by the teachings of Nishimoto and/or Takahashi to substitute an aqueous solution consisting essentially of hinokitiol for the peracetic acid solution of Kurschner in the absence of some objective teaching that such a substitution would be either prudent or rational in view of possible adverse effects upon the poultry meat so treated" (id. at 14). Appellant further argues that "[d]espite the fact that Nishimoto and Takahashi may teach the use of a sterilizing agent to sterilize various goods or devices, one of ordinary skill in the art would not equate such teachings with the sterilization of food" because "one of ordinary skill in the art recognizes that great care is exercised when using sterilizing compositions for food to avoid compromising the edibility of the food" (id.).

We are not persuaded by this argument. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR Int'l Co. v. Teleflex Inc., 127

S. Ct. 1727, 1739 (2007). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 1740.

As discussed above, hinokitiol was a known antibacterial agent with a known suitability for use with meat and kitchen utensils. The combination of the known antibacterial agent, hinokitiol, in an art-recognized poultry treatment process appears to be nothing more than the combination of old elements for their expected function to yield predictable results.

With regard to claims 13-15, 19-21, and 24, Appellant argues that the prior art fails to disclose or suggest the use of such a sterilizing agent in the amount of from 1 to 50,000 ppm (claim 13, 19 and 24), a pH of from 4 to 11 (claim 14, 20, and 24), a contacting temperature of from 0° to 70°C (claim 15, 21, and 24) (Appeal Br. 15-17).

We do not find this argument to be persuasive. Kurschner teaches that preferred conditions for sanitizing poultry meat include a temperature of 10° C to 27° C and a pH of 3-5 (Kurschner, col. 9, II. 35-48). In addition, Nishimoto exemplifies the antibacterial effect of hinokitiol solutions containing 0.5%, 0.05%, and 0.005% by weight against various bacteria (Nishimoto, col. 11, I. 60 to col. 15, I. 35). The concentrations used by Nishimoto correspond to 5000 ppm, 500 ppm, and 50 ppm, respectively. Thus, the ranges recited in claims 13-15, 19-21, and 24 overlap the ranges taught in the prior art. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)("A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.").

With regard to claim 17, Appellant argues that the cited prior art fails to disclose or suggest that the contact treatment is carried out during, for example, an interval between an evisceration step and a chilling step, as required by claim 17 (Appeal Br. 16).

We do not find this argument to be persuasive. As set forth above, Kurschner discloses that the anti-bacterial agent may be applied immediately following evisceration (Kurschner, col. 3, Il. 26-31). Kurschner also discloses that evisceration is typically followed by chilling in during poultry processing (*id.* at col. 1, Il. 12-16). Thus, one of skill in the art would understand that application of the anti-bacterial agent immediately after evisceration would be between an evisceration step and a chilling step.

With regard to claim 26, Appellant argues that the prior art fails to suggest the presence of a surfactant (Appeal Br. 15).

We are not persuaded by this argument. Takahashi discloses that "other components that are generally used for foods, pharmaceuticals, quasidrugs, cosmetics or the like, acidity control agents, stabilizers, surfactants, ..." can be mixed with the anti-bacterial agent of the invention (Takahashi at col. 6, Il. 20-23). Thus, one of skill in the art would have considered it obvious to include a surfactant in a hinokitiol composition used in poultry processing.

With regard to claim 27, Appellant argues that the prior art fails to suggest a plant extract (Appeal Br. 15).

We are not persuaded by this argument. Takahashi specifically suggests a eucalyptus plant extract as an anti-bacterial agent for meat treatment (Takahashi, abstract; col. 7, 1l. 49-54), and suggests that the

eucalyptus extract can be combined with hinokitiol to form a more powerful anti-bacterial agent (*id.* at col. 6, ll. 26-29). Thus, one of skill in the art would have considered it obvious to include a plant extract in a hinokitiol composition used in poultry processing.

With regard to claim 25, Appellant argues that the cited prior art fails to disclose or suggest a method of contacting un-sterilized poultry meat with a hinokitiol solution and then "wrapping the carcass and/or the meat without removal of the residue of hinokitiol solution on the meat; thereby producing sterilizing, wrapped, poultry meat without adversely affecting either the color or the taste of the meat" (Appeal Br. 18).

We are not persuaded by this argument. In addition to the disclosure set forth above, Kurschner discloses that "excess peracetic acid can be left on the fowl to ensure sanitation" (Kurschner at col. 2, ll. 1-2). Further, as discussed above, Takahashi discloses that hinokitiol can be used in a composition for sterilizing meat and that such compositions can keep meat fresh for a long time since it can inhibit propagation of the bacterium on the surface of the meat for a long time. Thus, given that hinokitiol is recognized in the art as being safe for use on meat, as discussed above, one of skill in the art would understand that at least some residue of the anti-bacterial hinokitiol agent used in a poultry treatment process need not be removed from the poultry.

Appellant further argues that, even if a prima facie case of obviousness has been established, the evidence of record overcomes any prima facie case of obviousness. Appellant cites both data in the

Specification and two declarations as providing evidence to overcome the prima facie case of obviousness.

First, Appellant argues that Table 1 and Figures 3-7 of the Specification provide evidence that "the present invention unexpectedly provides a safer and more effective sterilization method for poultry meat in comparison to the use of an aqueous hypochlorite solution" (Appeal Br. 19). Appellant argues that "[a]n aqueous solution of hinokitiol is shown to be overall more effective than hypochlorite in reducing the level of bacteria in treated chicken meat, while the aqueous solution of hinokitiol is orders of magnitude more effective with respect to certain of the treated bacteria" (id.).

We are not persuaded by this argument. "Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031(Fed. Cir. 1986). However, 'it is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice.' *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

In the instant situation, Appellant's argument that the claimed method provides unexpected results is not supported by factual evidence. The Specification shows that, in a single experiment, a hinokitiol solution was somewhat more effective in sterilizing chicken meat than a hypochlorite solution (at 50 mg/L). The Specification's Table 1 shows that the results

ranged from marginally better against *S. typhimurium* to about 30-fold better against *L. monocytogenes*.

However, the Specification does not assert that the results of the comparison between the hinokitiol solution and the hypochlorite solution in anti-bacterial effect were unexpected. Nor are the results characterized as unexpectedly superior in any of the declarations in the record. The only place the results are characterized as unexpected is in Appellant's brief. Attorney argument, however, is not evidence. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974). Because we find that the record does not show evidence that the claimed method provides *unexpectedly* superior results compared to the prior art, we conclude that the prima facie case of obviousness has not been overcome by a showing of unexpected results.

Second, Appellant argues that the submitted Declarations⁴ "demonstrate that the use of hinokitiol as a disinfectant unexpectedly does not adversely affect the color" or taste of poultry meat and that this result is not taught by the cited prior art (Appeal Br. 19). Appellant argues that the Iwai Declaration demonstrates that "the treatment of chicken breast meat with an aqueous solution of hinokitiol does not affect the color of the chicken breast meat" and "does not substantially affect the taste of the meat" (id.).

Appellant also argues that the Atarashi Declaration demonstrates that "no adverse 'whitening' of the poultry meat occurs upon being contacted

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⁴ Appellant cites the declarations under 37 C.F.R. § 1.132 of Kazuo Iwai signed April 8, 2003 (date-stamped May 6, 2003), and of Kunio Atarashi signed Sept. 30, 2003 (date-stamped Oct. 16, 2003).

with an aqueous solution of hinokitiol, and also that no irritable odor is caused to occur in the poultry meat" as compared to treatment with peracetic acid, which caused "advanced whitening of the meat after only 0.5 hour" and the presence of an irritating odor (id. at 19-20).

We are not persuaded by these arguments. "[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). Here, the data shown in the Iwai Declaration do not present a comparison of the prior art peracetic acid treatment disclosed by Kurschner, and therefore the data do not represent a comparison with the closest prior art.

The data in the Atarashi Declaration likewise does not compare the claimed method with the closest prior art. The Atarashi Declaration compares treatment of chicken meat with hinokitiol (125 or 1000 ppm) to treatment with peracetic acid (100, 500, or 1000 ppm), with appearance compared after 0.5, 2, 4, and 24 hours of treatment, and smell compared after 4 hours of treatment (Atarashi Declaration, pages 2 and 3). The results are disclosed to show that hinokitiol produced no whitening above that produced by water, while peracetic acid produced whitening (*id.* at 4). Hinokitiol treatment is also reported to cause no irritable odor, while peracetic acid caused irritable-odor in a concentration dependent manner (*id.* at 13). The results are stated to be unexpected with regard to Kurschner and Nishimoto (*id.* at 15).

However, the Atarashi Declaration does not provide a comparison of the claimed invention with the method suggested by the prior art. The instant claims do not require treatment of poultry meat for 0.5, 2, 4, or 24 hours, as in the Atarashi Declaration. Kurschner, as well, does not teach treatment for these periods of time. See Kurschner at col. 3, Il. 41-47 ("an application time equal to or greater than 0.5, 1, 5, 10, or 15 minutes") and col. 9, 1. 47 (effective exposure time is 30 sec to 10 min, preferred exposure time is 1 min to 5 min). The Atarashi Declaration establishes a difference between peracetic acid treatment and hinokitiol treatment only after a thirty minute treatment time. Therefore, the record as currently constituted does not establish that the claimed method provides unexpectedly superior results to methods that are the closest prior art.

SUMMARY

The Examiner's rejection is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 11-22 and 24-27 under 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

<u>AFFIRMED</u>

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BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH VA 22040-0747